PATENT
Docket No. MLI-10

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BOARD OF PATENT APPEALS AND INTERFERENCES

Applicants:	Michael D. Ries, et al.	)	
Serial No.:	10/763,314	)	
Filed:	January 22, 2004	)	Group Art Unit: 3738
For:	FEMORAL HIP PROSTHESIS AND METHOD OF IMPLANTATION	)	
Examiner:	Bruce E. Snow	)	

APPELLANTS' APPEAL BRIEF UNDER 37 CFR § 41.37

Mail Stop Appeal Brief
Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Dear Sir:

I. Real Party in Interest

The real party in interest in this case is Smith & Nephew, Inc.

II. Related Appeals and Interferences

There are no appeals or interferences which will directly affect or be directly affected or have a bearing on the Board's decision in the pending appeal.

III. Status of Claims

The present application was filed with 42 claims. Claims 43-57 were added by amendment. Claims 11, 19 and 21-39 have been canceled. Claims 1-10, 12-18, 20 and

40-57 are pending, rejected, and under appeal. Claims 1, 40, 41 and 42 are independent claims.

IV. Status of Amendments Filed Subsequent to Final Rejection

An amendment was filed on January 10, 2007. However, in an Advisory Action mailed on February 8, 2007, the Examiner indicated that this amendment would not be entered.

V. Summary of Claimed Subject Matter

(Please note: the application paragraph numbers referenced in this section and the remainder of the brief refer to the paragraph numbers in the application as filed. In the published application, the paragraph numbers are off by two: if a reader is viewing the published application, the reader must add two to each paragraph number to reference the correct paragraph.)

Claim 1 is directed to a femoral hip prosthesis 50 adapted for implantation against a resected surface 20 on a proximal end of a femur 10, and also in an intramedullary cavity 25 of the femur (Fig. 1, paragraph 23). The femoral hip prosthesis 50 comprises a femoral head component 700 and a femoral stem component 100 (Fig. 1, paragraph 23). The femoral head component 700 comprises an external bearing surface 710 (Fig. 3, paragraph 30). The femoral stem component 100 comprises a neck portion 150, a flange portion 200, a transitional body portion 300, and an elongated stem portion 400 (Fig. 1, paragraph 23). The neck portion 150 comprises a proximal portion 152 and a distal neck body 160 (Fig. 4, paragraphs 31, 32). The flange portion 200 is distal and adjacent to the neck portion 150 and comprises a bottom surface 220 (Fig. 4, paragraphs 34, 35). The

transitional body region 300 is adjacent to the bottom surface 220 of the flange portion 200 and also extends from the distal neck body 160 (Fig. 4, paragraph 35). The elongated stem portion 400 extends distally from the transitional body region 300 and is aligned with a longitudinal axis 425 (Fig. 4, paragraphs 38, 39). The longitudinal axis 425 is oriented at an acute angle 430 relative to the bottom surface 220 of the flange portion 200 (Fig. 4, paragraphs 26, 33). The transitional body region 300 is shaped to flex such that the bottom surface 220 of the flange portion 200 exerts a significant compressive load on the resected surface 20 of the femur 10 during a normal gait cycle (Figs. 1, 6, paragraphs 36, 37, 46).

Claim 40 is directed to a femoral hip prosthesis 50 adapted for implantation against a resected surface 20 on a proximal end of a femur 10, and also in an intramedullary cavity 25 of the femur (Fig. 1, paragraph 23). The femoral hip prosthesis 50 comprises a femoral head component 700 and a femoral stem component 100 (Fig. 1, paragraph 23). The femoral head component 700 comprises an external bearing surface 710 (Fig. 3, paragraph 30). The femoral stem component 100 comprises a neck portion 150, a flange portion 200, and an elongated stem portion 400 (Fig. 1, paragraph 23). The neck portion 150 is shaped to extend outside of the cavity of the femur and comprises a proximal portion 152 and a distal neck body 160 (Fig. 4, paragraphs 31, 32). The flange portion 200 projects distally and medially from the neck body 160, and comprises a bottom surface 220 (Fig. 4, paragraph 35). The elongated stem portion 400 extends inside the cavity of the femur, extends distally from the neck body 160, and is aligned with a longitudinal axis 425 (Fig.4, paragraphs 38, 39). The longitudinal axis 425 is oriented at an acute angle 430 relative to the bottom surface 220 of the flange portion 200

(Fig. 4, paragraphs 26, 33). Distal of a medial tip of the flange 200, each cross sectional shape along most of the elongated stem portion 400 is radially symmetrical (Figures 4, 4a-4e, paragraph 40).

Claim 41 is directed to a femoral hip prosthesis 50 adapted for implantation against a resected surface 20 on a proximal end of a femur 10, and also in an intramedullary cavity 25 of the femur (Fig. 1, paragraph 23). The femoral hip prosthesis 50 comprises a femoral head component 700 and a femoral stem component 100 (Fig. 1, paragraph 23). The femoral head component 700 comprises an external bearing surface 710 (Fig. 3, paragraph 30). The femoral stem component 100 comprises a neck portion 150, a flange portion 200, and an elongated stem portion 400 (Fig. 1, paragraph 23). The neck portion 150 is shaped to extend outside of the cavity of the femur and comprises a proximal portion 152 and a distal neck body 160 (Fig. 4, paragraphs 31, 32). The flange portion 200 projects distally and medially from the neck body 160, and comprises a bottom surface 220 (Fig. 4, paragraph 35). The elongated stem portion 400 extends inside the cavity of the femur, extends distally from the neck body 160, and is aligned with a longitudinal axis 425 (Fig.4, paragraphs 38, 39). The longitudinal axis 425 is oriented at an acute angle 430 relative to the bottom surface 220 of the flange portion 200 (Fig. 4, paragraphs 26, 33). Distal of a medial tip of the flange 200, most of the length of the elongated stem portion is circumscribed by a cylindrical shape (Figures 4, 4a, paragraph 40).

Claim 42 is directed to a femoral hip prosthesis 50 adapted for implantation against a resected surface 20 on a proximal end of a femur 10, and also in an intramedullary cavity 25 of the femur (Fig. 1, paragraph 23). The femoral hip prosthesis

50 comprises a femoral head component 700 and a femoral stem component 100 (Fig. 1, paragraph 23). The femoral head component 700 comprises an external bearing surface 710 (Fig. 3, paragraph 30). The femoral stem component 100 comprises a neck portion 150, a flange portion 200, and an elongated stem portion 400 (Fig. 1, paragraph 23). The neck portion 150 is shaped to extend outside of the cavity of the femur and comprises a proximal portion 152 and a distal neck body 160 (Fig. 4, paragraphs 31, 32). The flange portion 200 projects distally and medially from the neck body 160, and comprises a bottom surface 220 (Fig. 4, paragraph 35). The elongated stem portion 400 extends inside the cavity of the femur, extends distally from the neck body 160, and is aligned with a longitudinal axis 425 (Fig.4, paragraphs 38, 39). The longitudinal axis 425 is oriented at an acute angle 430 relative to the bottom surface 220 of the flange portion 200 (Fig. 4, paragraphs 26, 33). Distal of a medial tip of the flange 200, any two cross sectional widths of the stem portion, when measured perpendicular to the longitudinal axis, do not differ by more than ten percent (Fig. 4).

VI. Grounds of Objection/Rejection to be Reviewed on Appeal

A. The rejection of claims 1-10, 12-18, 20, 42-57 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

B. The rejection of claims 40-42, 45-57 under 35 U.S.C. 102(e) as being anticipated by U.S. Patent 6,514,288 to Meulink et al.

VII. Argument

A. Rejection under 35 U.S.C. 112, first paragraph

Claims 1-10, 12-18, 20

Claims 1-10, 12-18, and 20 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The Examiner states in regard to Claim 1 that "shaped to flex such that, during a normal gait cycle, ..." is not found in the original disclosure. However, this language is fully supported by Appellants' specification as filed. "[T]he failure of the specification to specifically mention a limitation that later appears in the claims is not a fatal one when one skilled in the art would recognize upon reading the specification that the new language reflects what the specification shows has been invented." *All Dental Prodx LLC v. Advantage Dental Products, Inc., 309 F.3d 774, 780 (Fed. Cir. 2002).* This test has clearly been met in the instant case.

More precisely, Appellants' specification, paragraphs 36-37, clearly describes the flexure of the stem component 100 and the transitional body region 300: "As the hip joint is loaded during clinical use, loads are transmitted through the male friction fit portion 154 and distal neck body 160 to the flange portion 200 and the transitional body portion 300 to the stem. Since the transitional body portion 300 is relatively flexible and not as bulky and rigid as a conventional femoral hip prosthesis, the transitional body portion 300 allows the femoral stem component 100 to flex and transmit the compressive load to the bone in the calcar region 11 of the proximal femur 10."

Patient gait is the clear context underlying the transmission of such loading. Specifically, paragraph 46 provides: "The distribution of the magnitude and direction of

these force components depend upon complex combinations of biomechanical factors such as leg stance, patient weight distribution, and patient gait. The femoral stem component 100 is designed to translate these forces to anatomic loads on the proximal femur 10." Furthermore, the phrase "[a]s the hip joint is loaded during clinical use..." provided in paragraph 37 would be understood by those skilled in the art to refer to postoperative use within a patient. Appellants assert that the requirements of 35 U.S.C. 112, first paragraph are met by the original disclosure.

Although the Final Office Action being appealed does not object to this language, Appellants wish to point out that the language "the bottom surface exerts a significant compressive load on the resected surface of the femur" from claim 1 is also well-supported by the specification as filed, and meets the text set forth in *All Dental Prodx, LLC v. Advantage Dental Prods., Inc.*, which was quoted above. More precisely, paragraph 37 provides the following:

> "This dynamic flexibility within the transitional portion 300 is desired since it allows the flange portion 200 of the femoral stem component 100 to transmit loads and displacements to the femoral calcar region 11 of the proximal femur 10. When bone is loaded and allowed to deform, a piezoelectric effect within the tissue simulate the bone cells into further production. This phenomenon, sometimes called Wolfs Law, coupled with other physiologic and biochemical principles, helps to keep the bone surrounding the femoral hip prosthesis 50 healthy and vibrant.

This language clearly supports and discloses the exertion of a significant compressive load on the resected surface of the femur. It also provides context to the term "significant" to one of skill in the art because the loads transmitted are to be sufficient to stimulate the bone cells into further production.

Paragraph 37 further states "[s]ince the transitional body portion 300 is relatively flexible and not as bulky and rigid as a conventional femoral hip prosthesis, the transitional body portion 300 allows the femoral stem component 100 to flex and transmit the compressive load to the bone in the calcar region 11 of the proximal femur 10." As quoted above, paragraph 46 of Appellants' specification reads "[t]he femoral stem component 100 is designed to translate these forces to anatomic loads on the proximal femur 10." These passages further support the language of claim 1, as amended, and provide sufficient context to make the meaning of the limitations clear to one of skill in the art, particularly where no prior art has been cited that would require the claim terminology to be narrowly defined. Appellants note that, in the Final Office Action, no prior art has been cited against claim 1.

Claim 42

Claim 42 stands rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The Examiner states in regard to claim 42 that "...do not differ by more than ten percent..." appears to be new matter. This is not new matter, as this language is very similar to the original text of claim 42, which read "...wherein the elongated stem portion does not vary in its maximum cross sectional width by more than ten percent." Appellants assert that claim 42 does not contain new matter, and that the requirements of 35 U.S.C. 112, first paragraph are met.

Claim 43

Claim 43 stands rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, for being new matter. Claim 43 is not new matter, because it is supported by the text of original claim 21: "...an elongated stem

portion, extending distally from the transitional body region and substantially aligned with a longitudinal axis that is at an acute angle from the bottom surface of the flange portion, the elongated stem portion having a uniform envelope with a maximum cross-section outer periphery dimension;...wherein the transitional body region has a maximum height, measure normal from the bottom surface of the flange to any part of the transitional body region, the height is less than the diameter of the maximum cross-section outer periphery dimension." Paragraph 38 further supports the claim: "The elongated stem portion is encompassed within a cylindrically shaped envelope referred to as uniform envelope 410. The cross-sectional shape and the area of the uniform envelope remains substantially uniform throughout the longitudinal length of the elongated body." Appellants assert that claim 43 does not contain new matter, and that the requirements of 35 U.S.C. 112, first paragraph are met.

Claim 44

Claim 44 stands rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, for being new matter. Claim 44 is not new matter, as it is clearly supported by Figure 4 and paragraph 35. Figure 4 shows that the transitional body region 300 is shaped to provide a lateral offset between an axis of the neck portion 150 and the longitudinal axis 425 of the elongated stem portion 400. As specified in paragraph 35, "The transitional body region 300 is the portion of the femoral stem component 100 that transitions from the distal neck body 160 and the flange portion 200 to the distal elongated stem portion 400." Figure 4 shows the transitional body region 300 shaped as having a 90° angle, which provides the offset between the longitudinal axis 425 of the elongated stem portion 400 and the axis of the neck portion 150. Appellants

assert that claim 44 does not contain new matter, and that the requirements of 35 U.S.C. 112, first paragraph are met.

Claim 45

Claim 45 stands rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, for being new matter. Claim 45 is not new matter, as it is supported by original claim 39, paragraph 40 and Figures 4, 4a-4e. Specifically, original claim 39 states "...preparing a non-eccentric, symmetric intramedullary cavity in the proximal femur...inserting a portion of the elongated stem portion of the femoral hip prosthesis in the intramedullary cavity..." A prosthesis intended to be inserted in a non-eccentric, symmetric intramedullary cavity would of necessity be non-eccentrically symmetrical itself.

Furthermore, paragraph 40 states "...the basic substantial shape of the external periphery of the cross-section of the elongated stem portion 400 remains uniform and circular. Thus, the elongated stem portion and the uniform envelope 410 are both substantially symmetric and non-eccentric." Figure 4 illustrates the elongated stem portion 400 distal of the medial junction of the neck portion 150 with the flange 200. The elongated stem portion is clearly radially symmetrical along substantially its entire length. Figures 4a-4e illustrate cross-sections of embodiments of the elongated stem portion; each cross-section is clearly radially symmetrical. Claim 45 is plainly supported by both the written description and drawings, and does not constitute new matter.

Claim 46

Claim 46 stands rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, for being new matter. Claim 46 is not

new matter, as it is illustrated in Figures 4a-4e and fully supported in paragraph 40: "The cross section of this cylindrically shaped elongated stem portion is shown in figure 4a. However, for other embodiments of the femoral stem component 100, the cross-sectional shape of the elongated stem portion 400 can be also non-circular shapes such as substantially square shape 920, as shown in figure 4b; a substantially triangle shape 930, as shown in figure 4c; a substantially hexagonal shape 940, as shown in figure 4c, a substantially star shape 950 as shown in figure 4e, or any other substantially non-eccentric, symmetric shape such as a tube (not shown) that can functionally form the cross-section of the elongated stem portion 400." Claim 46 is plainly supported by both the written description and drawings, and does not constitute new matter.

Claim 47

Claim 47 stands rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, for being new matter. Claim 47 is not new matter, as it is shown in Figure 5. The embodiment depicted in Figure 5 clearly shows that the elongated stem portion comprises a proximal section with a substantially circular shape, and a distal section with a non-circular cross sectional shape, as evidenced by the splines 460 and slot 480, whose presence create a non-circular cross sectional shape.

Claim 48

Claim 48 stands rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, for being new matter. Claim 48 does not constitute new matter, as it is supported by Figure 3. In Figure 3, element 410 (the parallel broken lines on either side of the elongated stem portion 400) clearly demarcates

the cylindrical shape of the elongated stem portion distal of the medial tip of the flange. Furthermore, paragraph 38 states: "The elongated stem portion is encompassed within a cylindrically shaped envelope referred to as uniform envelope 410." Claim 48 is plainly supported by both the written description and drawings, and does not constitute new matter.

Claim 49

Claim 49 stands rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, for being new matter. This is not new matter, as this language is very similar to the original text of claim 42, which read "...wherein the elongated stem portion does not vary in its maximum cross sectional width by more than ten percent." Appellants assert that claim 49 does not contain new matter, and that the requirements of 35 U.S.C. 112, first paragraph are met.

Claim 50

Claim 50 stands rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, for being new matter. Claim 50 is not new matter, for the same reasons that claim 44 is not new matter.

Claim 51

Claim 51 stands rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, for being new matter. Claim 51 does not constitute new matter, as it is supported by Figure 3. In Figure 3, element 410 (the parallel broken lines on either side of the elongated stem portion 400) clearly demarcates the cylindrical shape of the elongated stem portion distal of the medial juncture of the neck portion with the flange. Furthermore, paragraph 38 states: "The elongated stem

portion is encompassed within a cylindrically shaped envelope referred to as uniform envelope 410." Claim 51 is plainly supported by both the written description and drawings, and does not constitute new matter.

Claim 52

Claim 52 stands rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, for being new matter. Claim 52 is not new matter, for the same reasons set forth above for claim 47.

Claim 53

Claim 53 stands rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, for being new matter. Claim 53 is not new matter, for the same reasons set forth above for claim 49.

Claim 54

Claim 54 stands rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, for being new matter. Claim 54 is not new matter, for the same reasons set forth above for claim 44.

Claim 55

Claim 55 stands rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, for being new matter. Claim 55 is not new matter, for the same reasons set forth above for claim 42.

Claim 56

Claim 56 stands rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, for being new matter. Claim 56 is not new matter, for the same reasons set forth above for claim 47.

Claim 57

Claim 57 stands rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, for being new matter. Claim 57 is not new matter, for the same reasons set forth above for claim 44.

B. Rejection under U.S.C. 102(e) over Meulink

Claims 40, 45, 50

Claims 40, 45 and 50 stand rejected under U.S.C. 102(e) as anticipated by Meulink. Meulink clearly does not disclose the apparatus recited in claims 40 and 50, because Meulink's Figures 8 and 9 only illustrate radial symmetry of the distal portions of the femoral shafts 36 and 36a, and not "along substantially an entire length" as recited in claim 40. More precisely, the section lines of Figures 2 and 3 clearly show that the section views of Figures 8 and 9 are taken approximately midway along the lengths of the femoral shafts 36, 36a. The proximal portions illustrated in Figures 2 and 3 clearly do not have radially symmetrical cross sectional shapes. When the side views of Figures 2 and 3 and considered simultaneously with the medial-lateral views of Figures 4 and 5, it is plain that proximal portions of the femoral shafts increase significantly in height (as seen in Figures 2 and 3) as they approach the shoulder, but increase little if at all from side to side (as seen in Figures 4 and 5). The cross section of the proximal portion of the femoral shaft clearly does not remain radially symmetrical as it approaches the shoulder. Appellants assert that Meulink does not disclose radial symmetry of the femoral shaft along "substantially an entire length", and therefore claims 40, 45 and 50 are not anticipated by Meulink.

Claims 41, 51, 54

Claims 41, 51 and 54 stand rejected under U.S.C. 102(e) as anticipated by Meulink. Meulink clearly does not disclose the apparatus recited in claims 41 and 54, because the femoral shafts 36, 36a shown in Figures 1, 2 and 3 do not show "...substantially an entire length of the elongated stem portion circumscribed by a substantially cylindrical shape". The proximal portions of femoral shafts 36, 36a have radial curves 32, 32a beginning at medial curve tangencies 34, 34a, which distort the shape of the shaft into a non-cylindrical shape. Specifically, Meulink states in col. 3, lines 60-65: "Medial curve tangency 34 comprises the portion of medial curve 32 tangent to cylindrical femoral shaft 36. In other words, medial curve tangency 34 is located at the point where medial curve 32 ends and cylindrical femoral shaft 36 begins." Meulink clearly admits that the cylindrical portion of the shaft begins at the tangency, and therefore does not extend "substantially an entire length" of the shaft. Appellants assert that Meulink does not teach "...substantially an entire length of the elongated stem portion circumscribed by a substantially cylindrical shape", and therefore claims 41, 51 and 54 are not anticipated by Meulink.

Claims 42, 55, 57

Claims 42, 55 and 57 stand rejected under U.S.C. 102(e) as anticipated by Meulink. However, Meulink does not teach "...wherein, distally of a medial tip of the flange, any two maximum cross sectional widths of the elongated stem portion, measured perpendicular to the longitudinal axis, do not differ by more than ten percent." As shown in the side elevation views in Meulink's Figures 2, 3 and 10, the cross sectional widths of the femoral shafts 36, 36a, and 36d clearly differ by more than ten percent. Appellants

assert that Meulink does not teach a difference in cross sectional widths which do not differ by more than ten percent, and therefore claims 42, 55 and 57 are not anticipated by Meulink.

Claim 46

Claim 46 stands rejected under U.S.C. 102(e) as anticipated by Meulink. Appellants assert that Meulink does not teach "...each cross sectional shape is selected from the group consisting of a circle, a rectangle, a hexagon, and a star shape." Nowhere does Meulink teach a cross section that is a rectangle, a hexagon or a star shape. Moreover, a cross section of the proximal portion of the femoral shaft, as seen in Figures 2, 3 and 10, would result in a shape that is neither a circle, a rectangle, a hexagon or a star.

Claim 47

Claim 47 stands rejected under U.S.C. 102(e) as anticipated by Meulink. Meulink does not teach "...the elongated stem portion comprises a proximal section having a substantially circular shape, and a distal section having a non-circular cross sectional shape." Instead, Figures 2, 3 and 10 teach the opposite orientation. The proximal sections of femoral shafts 36, 36a and 36d have a non-circular cross section, as explained above with regards to claims 40, 45 and 50. The distal ends of the femoral shafts do not have a non-circular shape, as is clearly shown in Figures 6, 7, 8 and 9.

Claim 48

Claim 48 stands rejected under U.S.C. 102(e) as anticipated by Meulink. Meulink does not anticipate claim 48, for the same reasons set forth above for claim 41.

Claim 49

Claim 49 stands rejected under U.S.C. 102(e) as anticipated by Meulink. Meulink does not anticipate claim 49, for the same reasons set forth above for claim 42.

Claim 52

Claim 52 stands rejected under U.S.C. 102(e) as anticipated by Meulink. Meulink does not anticipate claim 52, for the same reasons set forth above for claim 47.

Claim 53

Claim 53 stands rejected under U.S.C. 102(e) as anticipated by Meulink. Meulink does not anticipate claim 53, for the same reasons set forth above for claim 42.

Claim 56

Claim 56 stands rejected under U.S.C. 102(e) as anticipated by Meulink. Meulink does not anticipate claim 56, for the same reasons set forth above for claim 47.

Conclusion

In conclusion, for the arguments of record and the reasons set forth above, all pending claims of the subject application continue to be in condition for allowance and Appellants seek the Board's concurrence at this time.

Dated this 30th day of April, 2007.

Respectfully submitted,

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Dated this the 30th day of April, 2007.

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APPENDIX A

CLAIMS ON APPEAL

1. A prosthesis adapted for implantation against a resected surface on a proximal end of a femur and inside of an intramedullary cavity of the femur, the prosthesis comprising:

a femoral head component comprising an external bearing surface; and

a femoral stem component comprising:

a neck portion comprising a proximal portion, engagable with the femoral head component, and a distal neck body;

a flange portion distal and adjacent to the neck portion, the flange portion comprising a bottom surface;

a transitional body region adjacent to the bottom surface of the flange portion and extending from the distal neck body; and

an elongated stem portion extending distally from the transitional body region and having a longitudinal axis oriented at an acute angle from the bottom surface of the flange portion;

wherein the transitional body region is shaped to flex such that, during a normal gait cycle, the bottom surface exerts a significant compressive load on the resected surface of the femur.

2. A prosthesis as is claim 1, wherein the elongated stem portion comprises a uniform envelope with a substantially constant cross-sectional peripheral shape and size.

3. A prosthesis as in claim 1, wherein the elongated stem portion comprises a proximal section having a cross sectional shape that is substantially consistent along a longitudinal length of the proximal section, wherein a minimum displacement between the bottom surface of the flange and the proximal section, measured normal to the bottom surface, is less than thirteen millimeters.

4. A prosthesis as in claim 1, further comprising a rotation-restricting boss, extending from the bottom of the flange portion.

5. A prosthesis as in claim 2, further comprising a rotation-restricting boss, extending from the bottom of the flange portion.

6. A prosthesis as in claim 5, wherein the rotation restricting boss has an axis of protrusion with a boss axis origin near the bottom surface of the flange, the elongated stem also has a stem axis origin near the bottom of the flange, the boss axis origin and the stem axis origin are spaced apart by a length more than the maximum cross-section of the elongated stem portion.

7. A prosthesis as in claim 6, wherein the axis of protrusion and the longitudinal axis are substantially parallel.

8. A prosthesis as in claim 6, wherein the axis of protrusion and the longitudinal axis are not substantially parallel.

9. A prosthesis as in claim 6, wherein the axis of protrusion is normal to the bottom surface of the flange portion.

10. A prosthesis as in claim 1, wherein the elongated stem portion has a distal section with multiple longitudinal flutes, wherein the longitudinal flutes are aligned approximately parallel to the longitudinal axis.

11. (Cancelled)

12. A prosthesis as in claim 1, wherein the neck portion is aligned at an obtuse angle with respect to the bottom surface of the flange portion.

13. A prosthesis as in claim 12, wherein the obtuse angle is between 100° and 170°.

14. A prosthesis as in claim 1, wherein the neck portion has a first end and a second end, wherein the first end is connected to the flange portion and extends proximally therefrom and the second end is shaped to press-fit into the femoral head component.

15. A prosthesis as in claim 14, wherein at least a portion of the outer surface of the femoral head component is hemispherical.

16. A prosthesis as in clam 1, wherein the acute angle ranges from 15° to 80°.

17. A prosthesis as in claim 2, wherein the uniform envelope has a maximum cross-section area measured on a plane perpendicular to the longitudinal axis.

18. A prosthesis as in claim 1, wherein the elongated stem portion has a length of at least one hundred millimeters as measured along the length of its longitudinal axis.

19. (Cancelled)

20. A prosthesis as in claim 1, wherein the elongated stem portion_comprises a tapered portion.

21-39. (Cancelled)

40. A prosthesis adapted for implantation against a resected surface on a proximal end of a femur and inside of a cavity of the femur, comprising:

a femoral head component comprising an external bearing surface; and

a femoral stem component comprising:

a neck portion shaped to extend substantially outside the cavity of the femur, the neck portion having a proximal portion, engagable with the femoral head component, and a distal neck body;

a flange portion medially and distally projecting from the neck body, the flange portion comprising a bottom surface;

an elongated stem portion shaped to extend substantially inside the cavity of the femur and extending distally from the neck body and having a longitudinal axis oriented at an acute angle from the bottom surface of the flange portion;

wherein, distally of a medial tip of the flange, each cross sectional shape along substantially an entire length of the elongated stem portion is substantially radially symmetrical.

41. A prosthesis adapted for implantation against a resected surface on a proximal end of a femur and inside of a cavity of the femur, comprising:

a femoral head component comprising an external bearing surface; and

a femoral stem component comprising:

a neck portion shaped to extend substantially outside the cavity of the femur, the neck portion having a proximal portion, engagable with the femoral head component, and a distal neck body;

a flange portion medially and distally projecting from the neck body, the flange portion comprising a bottom surface;

an elongated stem portion shaped to extend substantially inside the cavity of the femur and extending distally from the neck body and having a longitudinal axis oriented at an acute angle from the bottom surface of the flange portion;

wherein, distally of a medial tip of the flange, substantially an entire length of the elongated stem portion is circumscribed by a substantially cylindrical shape.

42. A prosthesis adapted for implantation against a resected surface on a proximal end of a femur and inside of a cavity of the femur, comprising:

a femoral head component comprising an external bearing surface; and

a femoral stem component comprising:

a neck portion shaped to extend substantially outside the cavity of the femur, the neck portion having a proximal portion, engagable with the femoral head component, and a distal neck body;

a flange portion medially and distally projecting from the neck body, the flange portion comprising a bottom surface;

an elongated stem portion shaped to extend substantially inside the cavity of the femur and extending distally from the neck body and having a longitudinal axis oriented at an acute angle from the bottom surface of the flange portion;

wherein, distally of a medial tip of the flange, any two maximum cross sectional widths of the elongated stem portion, measured perpendicular to the longitudinal axis, do not differ by more than ten percent.

43. A prosthesis as in claim 1, wherein the elongated stem portion comprises a proximal section having a cross sectional shape that is substantially consistent along a longitudinal length of the proximal section, wherein a minimum displacement between the bottom surface of the flange and the proximal section, measured normal to the bottom surface, is less than a maximum cross sectional width of the elongated stem portion, measured perpendicular to the longitudinal axis.

44. A prosthesis as in claim 1, wherein the transitional body region is shaped to provide a lateral offset between an axis of the neck portion and the longitudinal axis of the elongated stem portion.

45. A prosthesis as in claim 40, wherein, distally of a medial juncture of the neck portion with the flange, each cross sectional shape along substantially the entire length of the elongated stem portion is substantially radially symmetrical.

46. A prosthesis as in claim 40, wherein each cross sectional shape is selected from the group consisting of a circle, a rectangle, a triangle, a hexagon, and a star shape.

47. A prosthesis as in claim 40, wherein the elongated stem portion comprises a proximal section having a substantially circular shape, and a distal section having a non-circular cross sectional shape.

48. A prosthesis as in claim 40, wherein, distally of a medial tip of the flange, substantially an entire length of the elongated stem portion is circumscribed by a substantially cylindrical shape.

49. A prosthesis as in claim 48, wherein, distally of a medial tip of the flange, any two maximum cross sectional widths of the elongated stem portion, measured perpendicular to the longitudinal axis, do not differ by more than ten percent.

50. A prosthesis as in claim 40, wherein the femoral stem component further comprises a transitional body region adjacent to the bottom surface of the flange portion, wherein the transitional body region is shaped to provide a lateral offset between an axis of the neck portion and the longitudinal axis of the elongated stem portion.

51. A prosthesis as in claim 41, wherein, distally of a medial juncture of the neck portion with the flange, substantially the entire length of the elongated stem portion is circumscribed by the substantially cylindrical shape.

52. A prosthesis as in claim 41, wherein the elongated stem portion comprises a proximal section having a substantially circular shape, and a distal section having a non-circular cross sectional shape.

53. A prosthesis as in claim 41, wherein, distally of a medial tip of the flange, any two maximum cross sectional widths of the elongated stem portion, measured perpendicular to the longitudinal axis, do not differ by more than ten percent.

54. A prosthesis as in claim 41, wherein the femoral stem component further comprises a transitional body region adjacent to the bottom surface of the flange portion, wherein the transitional body region is shaped to provide a lateral offset between an axis of the neck portion and the longitudinal axis of the elongated stem portion.

55. A prosthesis as in claim 42, wherein, distally of a medial juncture of the neck portion with the flange, any two maximum cross sectional widths of the elongated stem portion, measured perpendicular to the longitudinal axis, do not differ by more than ten percent.

56. A prosthesis as in claim 42, wherein the elongated stem portion comprises a proximal section having a substantially circular shape, and a distal section having a non-circular cross sectional shape.

57. A prosthesis as in claim 42, wherein the femoral stem component further comprises a transitional body region adjacent to the bottom surface of the flange portion, wherein the transitional body region is shaped to provide a lateral offset between an axis of the neck portion and the longitudinal axis of the elongated stem portion.

APPENDIX B

EVIDENCE

None.

APPENDIX C

RELATED PROCEEDINGS

None.